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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,088	07/14/2003	Mark E. Steen	AMO0007	4690

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EXAMINER	
KOHARSKI, CHRISTOPHER	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
06/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/619,088	STEEN ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER D. KOHARSKI	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *77-86 and 109-148* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *77-86 and 109-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 2/19/2008 in which claims 77, 109, 119, 128, and 137 were amended. Currently claims 77-86 and 109-148 are pending for examination in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 77, 80-86, 109, 112-116, 119, 122-125, 128, 130-134, 137-139, and 141-146 are rejected under 35 U.S.C 103(a) as being unpatentable over Bylsma (6,319,220) in view of Dotson, Jr. (4,274,411).

Regarding claims 77, 80-86, 109, 112-116, 119, 1212-125, 128, 130-134, 137-139, and 141-146, Bylsma discloses a method and device for aspirating fluid from an ocular region during a phacoemulsification procedure (cols 2, 30-70; col

3, ln 1-30) comprising aspirating (4) the ocular region via a pressure system (17, peristaltic pump) to the ocular region via fluid control device (10) while applying ultrasonic energy with a needle (34), capable of producing cavitation (Figures 7-9). Bylsma further discloses delivering modulated ultrasound (see Figures 6-7)(col 4, ln 10-40) using an ultrasound phacoemulsification hand piece (30) (Figure 1).

Bylsma meets the claim limitations as described above except for the specific fluid control device creating a pressure pulse system for aspiration.

However, Dotson, Jr. discloses a fluid operated ophthalmic irrigation and aspiration device.

Regarding claims 77, 80-86, 109, 112-116, 119, 122-125, 128, 132-134, 137-139, and 141-146, Dotson, Jr. discloses a fluid operated method and device for aspiration of the ocular region (see abstract) using modulated differential pressure pulses via a fluid control device (Figures 1-3) (col 1, ln 50-67) (col 5, ln 15-55).

At the time of the invention, it would have been obvious to use the aspiration system of Dotson, Jr. with the system of Bylsma in order to provide a system that aids in the aspiration of hard to remove pieces of material (cols 1, ln 60-70) and the system of Dotson, Jr. is disclosed to be used with numerous types of hand piece systems (col 3, ln 1-20). The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Dotson, Jr. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 78-79, 85-86, 110-111, 117-118, 120-121, 126-127, 129-131, 135-136, 140-141 and 147-148 are rejected under 35 U.S.C 103(a) as being unpatentable over Bylsma (6,319,220) in view of Dotson, Jr. (4,274,411)

The modified Bylsma discloses the claimed invention except for the specific modulation pulse duration (100 milliseconds, 8 milliseconds, and 25, milliseconds).

Regarding claims 78-79, 85-86, 110-111, 117-118, 120-121, 126-127, 129-131, 135-136, 140-141 and 147-148, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the duration values as claimed by Applicant since the values as claimed lack criticality for the specific pulse times and duration and since Dotsonm, Jr. discloses the duration and pulse amounts can be varied to optimize removal of fragments (col 6, ln 20-60); additionally, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)*. See Gonan (6,423,028) for representative example illustrating varied pulse durations (Figures 1-10, col 4).

Response to Arguments

Applicant's arguments filed 2/19/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the combination of Bylsma in view of Dotson does not disclose the limitation such as "applying modulated differential fluid pressure pulses to the ocular region by deforming

aspiration tubing providing aspirating fluid from the ocular region" and uses hindsight and is an improper combination of references.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the references meet the claimed limitations of the pending claims. The Bylsma reference uses a peristaltic pump (17) which acts of the aspiration line (4) which moves fluid to the collection bag (5), the peristaltic pump acts of the aspiration by deforming the tube to create suction and therefore meets the claim limitation. In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Regarding the combination or references, the Examiner has clearly articulated the reason (see above rejection) to which one of ordinary skill in the art would apply. Both references describe that the pulsed modes allow for optimal use and extraction of tissue. The Bylsma reference discloses a system with for pulsed ultrasonic properties and the advantages thereof (cols 1-2), while the Dotson, Jr. reference discloses an aspiration system commonly used with ultrasound systems (35, col

1) with a pulsed aspiration mechanism and the advantages thereof (col 1, 60-70). Again as previously stated, the Examiner asserts that references are proper and the combination is proper.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification to the pulse procedure or structural elements that define the aspiration components.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 6/23/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763